KARL STORZ—ENDOSKOPE

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUN 11 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:	Karl Storz Endoscopy-America, Inc 2151 E. Grand Avenue El Segundo, CA 90245
Contact:	Leigh Spotten Regulatory Affairs Manager Phone: (424) 218-8738 Fax: (424) 218-8519
Date of Preparation:	May 08, 2014
Device Identification:	Trade Name: Flexible Ureteroscope Common Name: Flexible Video-Uretero-Renoscope System Classification Name: Ureteroscope and Accessories, Flexible/ Rigid
Product Code:	FGB
Regulation:	21 CFR part 876.1500
Predicate Device(s):	KARL STORZ Flexible Video-Uretero-Renoscope System, K131369
Device Description:	The Flexible Video-Uretero-Renoscope System is used for visualization purposes during diagnostic and therapeutic procedures. The system components are the Flexible Video-Uretero-Renoscope and the Image 1 SPIES Camera Control Unit (CCU). The Flexible Video-Uretero-Renoscope uses an LED light integrated in the handle and fiber light guides to illuminate the cavity under examination. The video image is produced by a complementary metal–oxide–semiconductor (CMOS) imaging sensor is located at the tip of the insertion shaft. The imaging sensor transfers the video signal to the Image1 SPIES CCU via electronics in the handle. The Image1 HD CCU processes the sensor images and displays them on a standard HD display monitor. The modifications made to the Flexible Video-Uretero-Renoscope System (K131369) are the conversion to the

	Image 1 SPIES CCU (K135319), material changes for STERRAD compatibility, a reduction in the insertion portion from 700mm to 675mm, and revision of the reprocessing instructions.
Indications For Use:	The KARL STORZ Flexible Video-Uretero-Renoscope System is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures
Technological Characteristics:	The Karl Storz modified Flexible Video-Uretero-Renoscope System has the same indications for use as the originally cleared Karl Storz Flexible Video-Uretero-Renoscope System (K131369). The methods of operation, design and materials used are either identical or substantially equivalent to existing legally marketed predicate devices
Non-Clinical Performance Data:	The modifications incorporated into the KARL STORZ Flexible Video-Uretero-Renoscope System have been evaluated according to ISO 14971 risk management process and the system was successfully tested for its functions and performance; including verification of optical characteristics per ISO 8600 (image quality, illumination). Safety testing was performed including electrical safety IEC 60601-1, electromagnetic compatibility per IEC 60601-1-2, and biocompatibility of the patient contacting materials per ISO 10993. Additional validations were conducted for the manual cleaning method, sterilization process.
Clinical Performance Data:	Clinical testing was not required to demonstrate substantial equivalence to the predicate device.
Conclusion:	The modified Flexible Video-Uretero-Renoscope System is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as or better than the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2014

Karl Storz Endoscopy-America, Inc.
Leigh Spotten
Regulatory Affairs Manager
2151 E. Grand Avenue
El Segundo, CA 90245-5017

Re: K141250
Trade/Device Name: Flexible Video-Uretero-Renoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: May 13, 2014
Received: May 14, 2014

Dear Leigh Spotten,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141250

Device Name: Flexible Video-Uretero-Renoscope System

Indications for Use:

The KARL STORZ Flexible Video-Uretero-Renoscope System is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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